

Appl. No. : **09/809,158**
Filed : **March 15, 2001**

REMARKS

Claims 3, and 57 have been canceled without prejudice to pursuing these claims in a different application. Claims 4, 5, 7, 9, 10, 37, and 42 are withdrawn. Claims 1, 6, 8, 11, 24, 52 and 55 have been amended. Support for the amendments can be found in the Specification and Claims as filed (see chart below). New Claims 58 and 59 have been added. Support for the new Claim can be found in the Specification and claims as filed. No new matter has been introduced herewith. Therefore, claims 1, 6, 8, 11, 13-19, 21-24, 27-31, 51-53, 55, 56 and 58 are presented for the examination.

Support Chart

Amended Claims	Support
Claim 1	16:19-27; 21:29-30; Claim 3
Claim 11	Claim 1; Claim 11
Claim 24	Claim 1
Claim 52	Claim 3
Claim 55	Claim 1
Claim 58	Claim 51
Claim 59	Claim 11

DISCUSSION

Claim rejections under 35 USC §112

The Examiner has rejected Claims 1, 3, 6, 8, 11, 13-16, 18, 21, 22, 23, and 27-31 under 35 U.S.C. §112, first paragraph. More specifically, the Examiner believes that the limitation of a lipophilic molecule that "does not induce contact dermatitis" was not present in the application as filed. The Applicant has now canceled Claim 3 and amended independent Claim 1 by deleting this limitation and introducing the limitations from the now canceled dependent Claim 3. The amended Claim 1 and Claims 6, 8, 11, 13-16, 18, 21, 22, 23, and 27-31 are therefore fully supported by the Specification as filed.

For all of the above, Applicant respectfully requests withdrawal of rejections of Claims 1, 3, 6, 8, 11, 13-16, 18, 21, 22, 23, and 27-31 under 35 U.S.C. §112, first paragraph.

Claim rejections under 35 USC §102

The Examiner has rejected Claim 24 under 35 U.S.C. §102(b) as being anticipated by Bauer et al..(US 4,036,952). The Applicant respectfully disagrees.

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To be anticipatory under 35 U.S.C. § 102, a reference must teach each and every element of the claimed invention. *See Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379 (Fed. Cir. 1986). “Invalidity for anticipation requires that all of the elements and limitations of the claim are found within a single prior art reference. ...There must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention.” *See Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565 (Fed. Cir. 1991).

Bauer et al. disclose a method for vaccinating a mammal comprising the topical application of inactivated virus or bacteria. Bauer et al. neither discloses nor even suggests that such topical application comprises a lipophilic molecule capable of traversing the stratum corneum and inducing dendritic cells to migrate to the draining lymphoid organ. Therefore, Bauer et al does not anticipate the amended Claim 24.

The Examiner has maintained the rejection of Claims 55 and 56 under 35 U.S.C. §102(b) as being anticipated by King et al. (Vaccine, 1987, 5:234-238). Applicant has amended Claim 55 to include the limitation “wherein the treatment comprises a lipophilic molecule with a molecular weight of \leq 500 daltons.” King et al. disclose a method for vaccinating a mammal against an antigen comprising delivering to nasal passages a topically applied live vaccine. King et al. does not disclose that his method of vaccinating comprises a lipophilic molecule with a molecular weight of \leq 500 daltons. Therefore, because King et al. does not anticipate the currently amended independent Claim 55, he also does not anticipate the dependent claim 56.

The Examiner has maintained rejection of Claim 1 and rejected Claim 20 under 35 U.S.C. §102(b) as being anticipated by Paul et al. (Vaccine Research 1995, Vol. 4:145-164) as evidenced by Roitt et al. (Immunology (text), 1993, pp. 8.3-8.4). The Applicant respectfully disagrees. Paul et al. states (page 147:17-18 and 25-26) that transferosomes "pass spontaneously through the microporous natural permeability barriers, including the intact mammalian skin" (emphasis added). Therefore, the penetration of stratum corneum by transferosomes is in fact opposite to the recited disruption of the stratum corneum. The Applicant respectfully points out that Claim 20 was canceled by the previous amendment filed on June 19, 2003, and its limitation was introduced in Claim 1. Furthermore, neither Paul et al. nor Roitt et al. disclose that the "topical treatment comprises a lipophilic molecule capable of traversing the stratum corneum and inducing immature dendritic cells to migrate to the draining lymphoid organ, and wherein said

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lipophilic molecule is ≤500 daltons and is selected from the following formulas..." Therefore, the Applicants respectfully assert that Claim 1 as amended is not anticipated by Paul *et al.* as evidenced by Roitt *et al.*

The Examiner has maintained rejection of Claims 52 and 53 under 35 U.S.C. §102(e) as being anticipated by Glenn *et al.* (USP 5,980,898). The Applicant respectfully disagrees. Glenn *et al.* discloses a method for vaccinating a mammal comprising an activator of Langerhans cells, wherein said activators include trinitrochlorobenzene, dinitrofluorobenzene, pentadecylcatecol and lipid A. Claim 52 as amended specifically recites: "said lipophilic molecule is ≤500 daltons and is selected from the following formulas:...", and therefore none of the compounds recited by Glenn *et al.* anticipate Claims 52 and 53.

For all of the above, Applicant respectfully requests withdrawal of all rejections of Claims 1, 24, 27, 52, 53, 55 and 56 under 35 U.S.C. §102 and allowance of the pending application.

Claim rejections under the judicially created doctrine of obviousness-type double patenting

The Examiner has maintained rejections of Claims 1, 3, 6, 8, 11, 13-19, 21-24, 27-31, 51-53 and 55-57 under the judicially created doctrine of obviousness-type double patenting as unpatentable over Claims 1-21 of USP 6,210,672. The Applicant acknowledges this rejection and reserves the right to file a terminal disclaimer once the pending claims are allowed by the Examiner.

Allowable Claims

Applicant wishes to thank the Examiner for her indication that Claims 17, 19 and 51 are allowable.

CONCLUSION

The Applicant has endeavored to address all of the Examiner's concerns as expressed in the outstanding Office Action. Accordingly, amendments to the claims, the reasons therefor, and arguments in support of the patentability of the pending claim set are presented above. Any claim amendments which are not specifically discussed in the above remarks are made in order to improve the clarity of claim language, to correct grammatical mistakes or ambiguities, and to otherwise improve the capacity of the claims to particularly and distinctly point out the invention to those of skill in the art. In light of the above amendments and remarks, reconsideration and

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withdrawal of the outstanding rejections is specifically requested. If the Examiner finds any remaining impediment to the prompt allowance of these claims that could be clarified with a telephone conference, the Examiner is respectfully requested to initiate the same with the undersigned.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: 12/11/03

By: 
Mark R. Benedict
Registration No. 44,531
Attorney of Record
Customer No. 20,995
(949) 760-0404

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